

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE SANOFI SECURITIES LITIGATION	:	Case No. 13 Civ. 8806 (PAE)
AG FUNDS, L.P., et al.,	:	Case No. 14 Civ. 2211 (PAE)
Plaintiffs,	:	ECF CASES
v.	:	
SANOFI, GENZYME CORPORATION, CHRISTOPHER VIEHBACHER, DAVID MEEKER, and JEROME CONTAMINE,	:	
Defendants.	:	

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**DECLARATION OF JOSHUA S. AMSEL IN SUPPORT OF  
DEFENDANTS' MOTIONS TO DISMISS THE COMPLAINTS**

I, Joshua S. Amsel, under penalty of perjury, declare as follows:

1. I am an attorney admitted to practice before this Court and a partner with the law firm of Weil, Gotshal & Manges LLP, attorneys for Defendants Sanofi, Genzyme Corporation, Christopher Viehbacher, David Meeker and Jérôme Contamine (collectively, "Defendants") in the above-captioned actions (the "Actions"). I submit this declaration in support of Defendants' motions to dismiss the complaints in the Actions.

2. True and correct copies of the following exhibits are attached hereto.

Exhibit	Description
1	Summary chart of claims and motion to dismiss arguments
2	Sanofi Registration Statement on Form F-4, filed with the U.S. Securities and Exchange Commission (the "SEC") on March 7, 2011 (excerpts)
3	Genzyme Alemtuzumab Advisory Committee Briefing Document for the Peripheral and Central Nervous System Drugs Advisory Committee (BLA 103948), dated

<b>Exhibit</b>	<b>Description</b>
	November 13, 2013 (excerpts) <available at <a href="http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM374188.pdf">http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM374188.pdf</a> >
4	Genzyme Press Release, October 14, 2010: Genzyme's Alemtuzumab Shows Sustained Reduction in Relapses and Disability in Five-Year Review of MS Patients from Phase 2 Trial
5	Genzyme Current Report on Form 8-K, filed with the SEC on February 16, 2011 (excerpts)
6	Sanofi Press Release, April 8, 2011: Sanofi-Aventis Completes Acquisition of Genzyme Corporation
7	U.S. Food and Drug Administration (“FDA”) Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products, dated May 1998 <available at <a href="http://www.fda.gov/downloads/Drugs/.../Guidances/ucm078749.pdf">http://www.fda.gov/downloads/Drugs/.../Guidances/ucm078749.pdf</a> >
8	FDA Drug Study Designs -- Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators <available at <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126501.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126501.htm</a> >
9	FDA Guidance for Industry: E10 Choice of Control Group and Related Issues in Clinical Trials, dated May 2001 <available at <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073139.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073139.pdf</a> >
10	FDA, Center for Drug Evaluation & Research: Manual of Policies & Procedures § 6025.4 <available at <a href="http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm370948.htm">http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm370948.htm</a> >
11	FDA Alemtuzumab Background Package for the Peripheral and Central Nervous System Drugs Advisory Committee Meeting (BLA 103948/5139), dated November 13, 2013 (excerpts) <available at <a href="http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM374186.pdf">http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM374186.pdf</a> >
12	U.S. National Institutes of Health (“NIH”): A Phase II Study Comparing Low- and High-Dose Alemtuzumab and High-Dose Rebif® in Patients with Early, Active Relapsing-Remitting Multiple Sclerosis <available at <a href="http://clinicaltrials.gov/ct2/show/NCT00050778">http://clinicaltrials.gov/ct2/show/NCT00050778</a> >
13	Transcript of Genzyme/ILEX Oncology Inc. meeting, March 1, 2004
14	Genzyme Press Release, September 16, 2005: Genzyme and Schering AG Announce

<b>Exhibit</b>	<b>Description</b>
	Interim Results from Trial of Campath for Multiple Sclerosis
15	Genzyme Press Release, September 14, 2006: Genzyme Reports Interim Results from Trial of Campath® for Multiple Sclerosis
16	Genzyme Press Release, October 15, 2007: Top-Line Efficacy Data Presented from Phase 2 Trial of Alemtuzumab in Multiple Sclerosis
17	Alasdair J. Coles, <i>et al.</i> , <i>Alemtuzumab vs. Interferon Beta-1a in Early Multiple Sclerosis</i> , 359 N. Eng. J. Med. 1786-1801 (October 2008)
18	Genzyme Press Release, April 14, 2010: Significant Percentage of MS Patients Receiving Alemtuzumab in Genzyme's Phase 2 Trial Remain Free of Clinically-Active Disease
19	Amendment 3 to Genzyme Solicitation/Recommendation Statement on Schedule 14D-9, filed with the SEC on October 18, 2010
20	Genzyme Press Release, September 26, 2007: Genzyme and Bayer Schering Pharma AG, Germany Announce Start of Phase 3 Program with Alemtuzumab for Treatment of Multiple Sclerosis
21	NIH: Comparison of Alemtuzumab and Rebif® Efficacy in Multiple Sclerosis, Study One (CARE-MS I) <available at <a href="http://clinicaltrials.gov/ct2/show/NCT00530348">http://clinicaltrials.gov/ct2/show/NCT00530348</a> >
22	NIH: Comparison of Alemtuzumab and Rebif® Efficacy in Multiple Sclerosis, Study Two (CARE-MS II) <available at <a href="http://clinicaltrials.gov/ct2/show/NCT00548405">http://clinicaltrials.gov/ct2/show/NCT00548405</a> >
23	Amendment 14 to Genzyme Solicitation/Recommendation Statement on Schedule 14D-9, filed with the SEC on December 23, 2010
24	Joint Sanofi-Genzyme Press Release, July 11, 2011: Sanofi Reports Positive Top-Line Results from First Phase 3 Study of Alemtuzumab (Lemtrada™) in Multiple Sclerosis
25	Joint Sanofi-Genzyme Press Release, October 22, 2011: Alemtuzumab (Lemtrada™) Significantly Reduces Relapses in Multiple Sclerosis vs Interferon Beta-1a in a Phase III Study
26	Sanofi Current Report on Form 6-K, filed with the SEC on November 14, 2011 (excerpts)
27	Sanofi Current Report on Form 6-K, filed with the SEC on April 25, 2012
28	Jeffrey A. Cohen, Alasdair J. Coles, <i>et al.</i> , <i>Alemtuzumab versus interferon beta 1a as first-line treatment for patients with relapsing-remitting multiple sclerosis: a randomized controlled phase 3 trial</i> , 380 Lancet 1819-28 (November 2012)

<b>Exhibit</b>	<b>Description</b>
29	Alasdair J. Coles, Cary L. Twyman, <i>et al.</i> , <i>Alemtuzumab for patients with relapsing multiple sclerosis after disease-modifying therapy: a randomized controlled phase 3 trial</i> , 380 Lancet 1829-39 (November 2012)
30	Sanofi Current Report on Form 6-K, filed with the SEC on March 25, 2013
31	Amendment 25 to Genzyme Solicitation/Recommendation Statement on Schedule 14D-9, filed with the SEC on March 7, 2011 (excerpts)
32	Genzyme Annual Report on Form 10-K, filed with the SEC on March 1, 2011
33	Genzyme Current Report on Form 8-K, filed with the SEC on January 11, 2011
34	Sanofi Annual Report on Form 20-F, filed with the SEC on March 6, 2012
35	Sanofi Current Report on Form 6-K, filed with the SEC on June 12, 2012 (excerpts)
36	Sanofi Current Report on Form 6-K, filed with the SEC on January 29, 2013 (excerpts)
37	Transcript of Genzyme-BayerHealth investor call, March 31, 2009
38	Sanofi 2012 Half-Year Financial Report, dated July 27, 2012 (excerpts)
39	Transcript of Sanofi SA Half Year 2012 earnings conference call, July 26, 2012
40	Transcript of Sanofi SA Q3 2012 earnings conference call, October 25, 2012
41	Transcript of Sanofi SA Full Year 2012 earnings conference call, February 7, 2013
42	Sanofi Annual Report on Form 20-F, filed with the SEC on March 7, 2013
43	Transcript of Sanofi SA Q2 2013 earnings conference call, August 1, 2013
44	European Medicines Agency Summary of Positive Opinion for Lemtrada, June 27, 2013 <available at <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/003718/WC500144904.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/003718/WC500144904.pdf</a> >
45	Joint Sanofi-Genzyme Press Release, September 17, 2013: European Commission Approves Genzyme's Multiple Sclerosis Treatment Lemtrada™ (alemtuzumab)
46	FDA Summary Minutes of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting on November 13, 2013, approved January 14, 2014 <available at <a href="http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM386058.pdf">http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM386058.pdf</a> >
47	Genzyme Press Release, December 30, 2013: Genzyme Receives Complete Response

<b>Exhibit</b>	<b>Description</b>
	Letter from FDA on Lemtrada™ (alemtuzumab) Application
48	Genzyme Press Release, December 13, 2013: Genzyme's Lemtrada™ Approved in Canada for Treatment of Multiple Sclerosis
49	Genzyme Press Release, December 19, 2013: Genzyme's Lemtrada™ Approved in Australia for Treatment of Multiple Sclerosis
50	Genzyme Press Release, February 4, 2014: Genzyme's Lemtrada® Approved in Mexico for Treatment of Multiple Sclerosis
51	Genzyme Press Release, March 21, 2014: Genzyme's Lemtrada™ Approved in Brazil for Treatment of Multiple Sclerosis
52	Joint Sanofi-Genzyme Press Release, April 7, 2014: Genzyme to Resubmit Lemtrada™ Application for FDA Review
53	Genzyme Press Release, May 30, 2014: Genzyme's Lemtrada Resubmission Accepted for Review by FDA
54	Sanofi Press Release, October 8, 2012: Sanofi Announces Final Results of its Modified Dutch Auction Tender Offer for its Outstanding Contingent Value Rights
55	Transcript of Bloomberg TV interview of Christopher Viehbacher, January 23, 2014
56	Compilation of statements of non-actionable puffery and optimism
57	Summary of cautionary language accompanying forward-looking statements
58	Genzyme Press Release, October 24, 2011: Sanofi Appoints David Meeker Chief Executive Officer of Genzyme
59	Transcript of Sanofi SA Q1 2012 earnings conference call, April 27, 2012
60	Joint Sanofi-Genzyme Press Release, October 31, 2012: Genzyme Announces Publication of LEMTRADA™ (alemtuzumab) Pivotal Studies in <i>The Lancet</i>
61	Transcript of Sanofi SA Q3 2013 earnings conference call, October 30, 2013
62	Transcript of Sanofi SA multiple sclerosis conference call, April 25, 2012
63	List of exhibits organized by date

3. I declare under penalty of perjury that the foregoing is true and correct.

Executed on: June 27, 2014

/s/ Joshua S. Amsel  
Joshua S. Amsel